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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/385,834	08/30/1999	JEFFREY L. C. WRIGHT	76891	9704

7590

07/16/2003

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/16/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/385,834

Applicant(s)

WRIGHT, JEFFREY L. C.

Examiner

Sabiha Qazi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,5-11,34 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,5-11,34 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 33&36.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Acknowledgement is made of the response filed in paper no. 32, declaration in paper no. 35, IDS in paper no. 33 and supplemental IDS in paper no. 36. Claims 1, 5-11, 34 and 39 are pending. No claim is allowed. Rejection under 112 (20 is withdrawn others are maintained for the same reasons as cited in our previous action.

The declaration filed on 5/5/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference. The arguments that Higgins III (US Patent 6,147,236) was filed on 12/15/1998 and issued on 11/14/2000 and the date of the present invention is prior to 12/15/1998 because of a communication of the inventor to the Attorney. It is unclear what invention was under consideration at that time. There is no proof that the claimed invention was conceived before 12/15/1998 by seeing the copy of the letter. Probably the conception of invention of Higgins III may be prior to 12/15/1998 as this is the filing date.

Even if there would have been a proof, when claims will be considered allowable than the Board of Interference will decide the issue of priority.

Applicant's arguments filed on 5/5/03 have been fully considered but were not persuasive. Examiner's rejection is based on only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Note, that the rejection is over combined teaching of the cited references. Therefore, argument of teaching of single reference is not considered a proper response. Examiner notes, that Applicants discuss references separately.

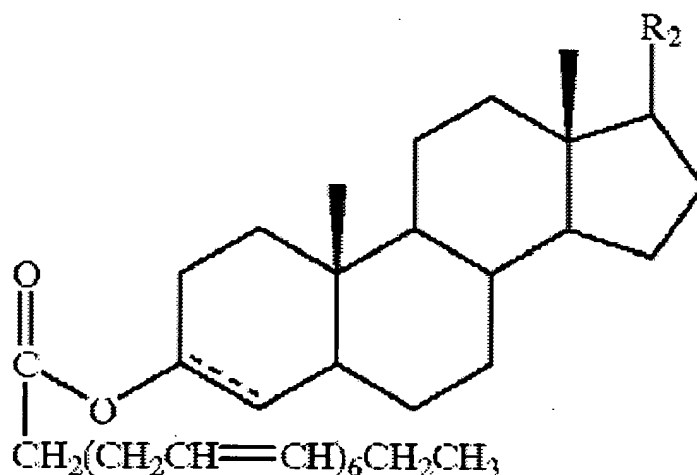
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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings.

In re opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

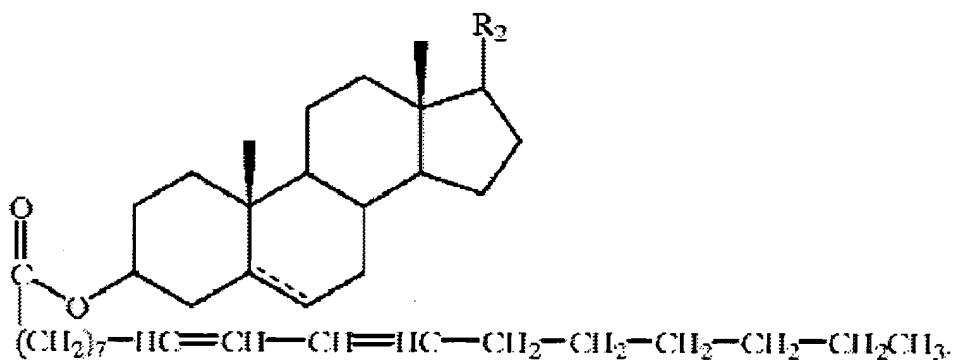
Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

Sterol/sterol docosahexaenoate, and more preferably



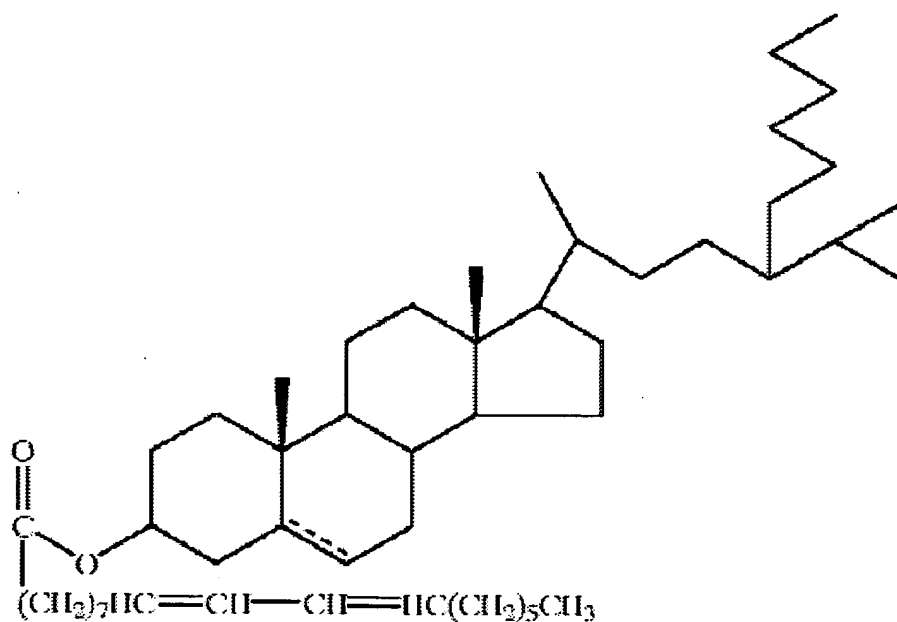
β -sitosterol docosahexaenoate; and
 β -sitostanol docosahexaenoate

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sterol/stanol octadecadienoate; the 9,11-octadecadienoic form is depicted above, and the 10,12 isomer is also common.

More preferably,

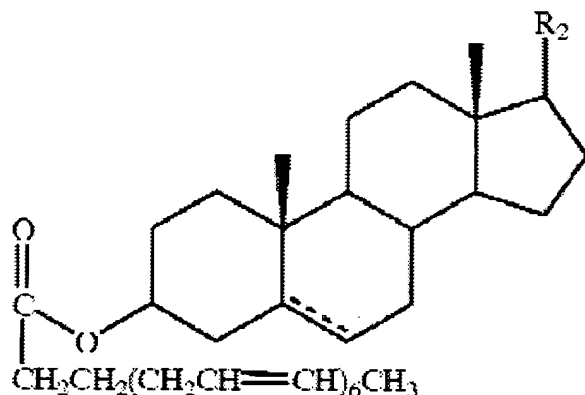


β -sistosterol octadecadienoate

Similarly

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Similarly, the ester product of DHA and sterol/stanol are provided below:



Examiner disagrees with the argument that Mishkel does not teach omega-3-fatty lowers the cholesterol. See last three paragraphs on page 632, Figure 3 on page 630. Mishkel teachings can be found in the article at several places. There too many to list. Examiner disagrees that "mishkel cites Davis et al. (1987) which teaches that omega-3 fatty acids from fish oil failed to reduce cholesterol levels". See Singer et al. (1987) which is cited by Mishkel where EPA was used for patients having mild hypertension. They observed a significant decline in systolic and diastolic pressures when compared to controls. Note, that fish oil contains EPA.

Rejection under 103 is maintained rejection is maintained because claimed invention is considered obvious at the time of invention.

No unexpected results are seen.

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Examiner notes that the paper used for declaration and response appears to be very brittle and is turning into pieces. Applicants should send the documents to this office in proper normal paper and not the brittle and old paper, which is breaking into pieces.

New copies of the declaration and amendments are required for the record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4556

for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



July 14, 2003

SABIHA QAZI, PH.D
PRIMARY EXAMINER